

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/13/2012 has been entered.

***Response to Amendment***

With respect to the amendment of claim 124 filed 01-13-2012, there is no discussion noted on page 19 of the specification that supports the amendment. There is a disclosure on pages 20-21 that "irradiated UHMMWPE is heated above the melting point so that there are substantially no detectable free radicals" in discussion of the WIR-SM embodiment that also employs a pre-heating step before irradiating the UHMWPE, as required in instant claim 124. Applicant discloses that the UHMWPE "is pre-heated to a temperature below the melting temperature of the UHMWPE" (page 21, second paragraph). There is no mention of "pre-heating to a temperature...less than the decomposition temperature of the UHMWPE" in the Specification as originally filed. There is no definition or description of the decomposition temperature of UHMWPE or of a method for determining the decomposition temperature of different kinds of UHMWPE. With respect to claims 124, 126, 127, 135-137: The terminology "reducing residual free radicals" is not found; thus applicant does not have support in the specification for the claim language "reducing residual free radicals in the crosslinked UHMWPE preform by heating the irradiated UHMWPE". What is disclosed is that "irradiated UHMMWPE is heated above the melting point so that there are substantially no detectable free

radicals” in discussion of the WIR-SM embodiment that also employs a pre-heating step before irradiating the UHMWPE, as required in instant claim 124. With respect to claims 135-137: the method disclosed comprises heating an irradiated preform to a temperature” above the melting point so that there are substantially no detectable free radicals”.

Applicant is reminded that applicant is required to use claim language that finds support in the specification as filed. For example, applicant discloses pre-heating UHMWPE to a temperature below the melting point and irradiating to crosslink followed by heating to obtain a product having “substantially no detectable free radicals”. It is the Examiner’s position that there is no basis for substituting the “reducing residual free radicals”, as set forth in the amended claims for the disclosure of “substantially no detectable free radicals” in the specification. Heating to simply reduce residual free radicals is not equivalent to the disclosure of melting to obtain a product having substantially no detectable free radicals.

***Response to Arguments***

Applicant's arguments filed 1/13/2012 have been fully considered but they are not persuasive.

Applicant argues that the term “quenching” generally refers to “reducing” residual free radicals. This argument is unpersuasive because what is disclosed is neither “quenching” nor “reducing” residual free radicals in irradiation crosslinked UHMWPE. What is disclosed in the instant specification as originally filed is a method wherein irradiation crosslinked UHMWPE is heated to a temperature above the melting point to obtain a product having substantially no detectable free radicals. Heating to reduce residual free radicals is not considered to be equivalent to heating a temperature above the melting point to arrive at substantially no

detectable free radicals. The amended claims, as written, are not supported by any disclosure of simply reducing free radicals to any possible degree or extent or by heating to temperatures lower than “above the melting point”.

**Written description and enablement rejections:** these rejections have been rewritten in response to applicant’s arguments for reconsideration and the newly amended claims. See the rejections herein below. With respect to **Examples 16-18** in the specification, each of these examples clearly discloses that the method steps employed are heating UHMWPE to a temperature below the melting point of the UHMWPE, irradiating the heated UHMWPE and subsequently melting the irradiated UHMWPE to provide a product having substantially no detectable free radicals. The methods disclosed in these examples does not provide basis for the claim language currently employed in the instant claims. The instant claims are not considered to be consistent with the disclosure in the instant specification when given their broadest interpretation consistent with the specification for the reasons set forth in the rejections herein below. Example 20, cited by applicant, discloses a method wherein the irradiated pucks are heated to a temperature above the melting point (150<sup>0</sup>C to completely melt the crystals) and the concentration of free radicals is reduced to undetectable levels, i.e. to substantially no detectable free radicals.

**Obviousness rejection over Sun et al:** Applicant argues that Sun et al do not disclose reducing free radicals in a crosslinked UHMWPE preform by heating irradiated UHMWPE. This argument is not persuasive for the following reasons. Sun et al specifically teach reducing free radicals remaining after irradiation by heat treatment followed by cooling (column 6, lines 48-51, and column 8, lines 11-20). Sun et al teach treating a polymeric component packaged in an air-

tight package. Applicant's claim language does not set forth any specific steps for reducing free radicals that distinguish the instantly claimed method from the irradiation and heating steps taught by Sun et al. As set forth in the rejection herein below: Sun et al teach a method for forming a medical implant comprising annealing a medical implant, corresponding to "pre-heating", and then radiation sterilizing the implant, corresponding to irradiating UHMWPE with crosslinking (column 5, lines 38-67, and column 6, lines 42-43). The irradiated implant is then further annealed to reduce free radicals, corresponding to reducing free radicals by heating irradiated UHMWPE (column 6, lines 48-51). Applicant discloses various fabricated articles, acetabular cups, tray shaped articles and compression molded parts without specifically defining a "pre-form" in a manner that would distinguish the instantly recited "pre-form" from the packaged implant disclosed by Sun et al.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 124-127 and 135-140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to **claims 124-125, 135 and 138**, the examiner has not found any disclosure of pre-heating "at a temperature greater than room temperature and less than the decomposition temperature for a period of time greater than about 30 minutes".

There is no disclosure of the **decomposition temperature** of UHMWPE in the instant disclosure. Applicant has not provided any direction with respect to determining the decomposition temperature of various samples of UHMWPE which UHMWPE samples may have been obtained by different methods and have different molecular weights and physical and chemical properties. Therefor, one skilled in the art would need to perform undue experimentation to determine the decomposition temperature of a given UHMWPE pre-form in order to determine the pre-heating temperature required in the instantly claimed method. No direction or examples are provided in the instant specification as guidance, nor is the decomposition temperature of a given UHMWPE pre-form considered to be predictable since it would be expected to vary according to such factors as the molecular weight of the UHMWPE and the method of forming the preform, at least. **With respect to instant claims 124-127 and 135-140**, the examiner has not found any disclosure of a method for reducing residual free radicals in an irradiation crosslinked UHMWPE preform by heating the irradiated UHMWPE. What applicant discloses is a method for heating irradiation crosslinked UHMWPE to a temperature above the melting point to obtain a product having substantially no detectable free radicals. See the description of the WIR-SM and WIR-AM methods on pages 20-21.

**Claims 124-127 and 135-140 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling.** Heating irradiated UHMWPE above the melting temperature of the UHMWPE after pre-heating and irradiating UHMWPE to crosslink the UHMWPE is disclosed as being critical or essential to the practice of the invention, in order to obtain a product having substantially no detectable free radicals, but is not included in the claim(s). Therefor the claims, as written, are not enabled by the disclosure. See *In re Mayhew*,

527 F.2d 1229, 188 USPQ 356 (CCPA 1976). There is no disclosure or example found in the specification, as originally filed, of method steps wherein UHMWPE crosslinked by irradiating the UHMWPE is simply heated to reduce residual free radicals. There is no guidance regarding the heating temperature or duration required or the extent or degree of reduction of residual free radicals desired or obtained. The disclosed methods are directed to obtaining a product having substantially no detectable free radicals by heating above the melting point of the UHMWPE, not to a method for simply reducing residual free radicals by heating, which encompasses heating at any temperature that increases the temperature of the UHMWPE and any degree of reduction of residual free radicals.

**Claims 124-127 and 135-140 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With respect to the amendment of claims 124-127 and 135-137 filed 01-13-2012, there is no discussion noted on page 19 of the specification that supports the claim language introduced by the amendment. Applicant discloses that the UHMWPE “is pre-heated to a temperature below the melting **temperature of the UHMWPE**” (page 21, second paragraph). **There is no mention of “pre-heating to a temperature...less than the decomposition temperature of the UHMWPE”** in the Specification as originally filed. There is no definition or description of the decomposition temperature of UHMWPE or of a method for determining the decomposition temperature of different kinds of UHMWPE. With respect to claims 124, 126, 127, 135-137: The terminology “reducing residual free radicals” is not found;

thus applicant does not have support in the specification for the claim language “reducing residual free radicals in the crosslinked UHMWPE preform by heating the irradiated UHMWPE”. What is disclosed is that “irradiated UHMWPE is heated above the melting point so that there are substantially no detectable free radicals” in discussion of the WIR-SM embodiment that also employs a pre-heating step before irradiating the UHMWPE, as required in instant claim 124. With respect to claims 135-137: the method disclosed comprises heating an irradiated preform to a temperature” above the melting point so that there are substantially no detectable free radicals”.

Applicant is reminded that applicant is required to use claim language that finds support in the specification as filed. For example, applicant discloses pre-heating UHMWPE to a temperature below the melting point and irradiating to crosslink followed by heating to obtain a product having “substantially no detectable free radicals”. It is the Examiner’s position that there is no basis for substituting the “reducing residual free radicals”, as set forth in the amended claims for the disclosure of “substantially no detectable free radicals” in the specification. Heating to simply reduce residual free radicals is not equivalent to the disclosure of melting to obtain a product having substantially no detectable free radicals.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 124-127 and 135-140 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** Instant **claims 124-127 and 135-140** fail to set forth that the method is a method for fabricating a **load bearing surface** for a medical prosthesis, as

set forth throughout the instant specification. The claims fail to clearly recite that the disclosed method comprising pre-heating UHMWPE requires **pre-heating at a temperature greater than room temperature and less than the melting point of the UHMWPE**. The instant claims fail to clearly recite that the heating step after irradiating a pre-heated UHMWPE sample requires **heating at a temperature above the melting point in order to obtain a product having substantially no detectable free radicals**. See the disclosure on pages 20-21 that “**irradiated UHMWPE is heated above the melting point so that there are substantially no detectable free radicals**” in discussion of the WIR-SM embodiment that also employs a pre-heating step before irradiating the UHMWPE. Applicant discloses that the UHMWPE “**is pre-heated to a temperature below the melting temperature of the UHMWPE**” (page 21, second paragraph). There is no mention of “pre-heating to a temperature...less than the decomposition temperature of the UHMWPE” in the Specification as originally filed. There is no definition or description of the decomposition temperature of UHMWPE or of a method for determining the decomposition temperature of different kinds of UHMWPE.

With respect to **claim 125**, the examiner has not found any disclosure of the recited “cooling the preform after the heating step to a **temperature below the melting temperature** of the irradiated UHMWPE”. Furthermore, claim 124 does not recite that the preheated and irradiated UHMWPE preform is heated to the melting point. What is disclosed in the specification is **cooling to room temperature** after the step of heating the pre-heated and irradiated UHMWPE preform to above the melting temperature to provide “no detectable free radicals in the UHMWPE”. See pages 20-21.

With respect to **claims 135-137**: the method disclosed comprises heating an irradiated preform to a temperature “above the melting point so that there are substantially no detectable free radicals”. A step of heating to a temperature above the melting temperature is disclosed in the specification on pages 14 and 21-22, wherein a method including the instantly claimed pre-heating is disclosed, i.e. a “WIR” embodiment, and requires heating the pre-heated and irradiated UHMWPE above the melting temperature of the UHMWPE after the irradiation step for obtaining substantially no detectable free radicals. No disclosure has been found of the recited heating the irradiated UHMWPE preform to a temperature “above room temperature” to reduce free radicals. Nothing in the specification, as filed, suggests that heating to 121<sup>0</sup>C, for instance, will reduce free radicals in the pre-heated and irradiated UHMWPE preform. What is disclosed in the instant specification is a method wherein, subsequent to irradiation, the irradiated UHMWPE is heated to a temperature above the melting temperature to provide a product having substantially no detectable free radicals. The method disclosed should be clearly set forth in the instant claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 124-127 and 135-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al (5,414,049).** Sun et al teach a method for forming a medical implant comprising annealing a medical implant and then radiation sterilizing the implant

(column 5, lines 38-67, and column 6, lines 42-43). The irradiated implant is then further annealed to reduce free radicals (column 6, lines 48-51). The difference from the instantly claimed process is that Sun et al teach treating a formed implant rather than a preform. It would have been obvious to one skilled in the art at the time of the invention to apply the process steps taught by Sun et al to a polyethylene preform. One of ordinary skill in the art at the time of the invention would have been motivated by a reasonable expectation of imparting the desirable properties taught by Sun et al to a preform material since the polymeric material is polyethylene in the implant and in the preform.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-126 and 128-134 of copending Application No. 10/948440.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. irradiating and heating a polyethylene article, are set forth in the claims of '440 and in the instant claims. The instantly claimed step of heating to a temperature less than the decomposition

temperature is considered to encompass the melting step set forth in the claims of ‘440. Alternatively, the melting step set forth in the claims of ‘440 corresponds to the step of quenching free radicals set forth in the instant claims and the comprising language of the claims of ‘440 encompasses the pre-annealing step in the instant claims. With respect to claims 138-140, claim 134 of Application ‘440 recites irradiation with a dose from about 5 to about 100 Mrad, thus encompassing the instantly claimed 4 to 30 Mrads. With respect to claims 126 and 127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of ‘440.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124, 126-129 and 135-137 of copending Application No. 10/197209.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the polyethylene, are set forth in the claims of ‘209 and in the instant claims. With respect to claims 126-127, It would have been obvious to one skilled in the art at the time of the invention to employ UHMWPE as the polyethylene in the method steps set forth in the claims of ‘209. With respect to claims 135-137, the comprising language of the claims of application ‘209 encompasses a step of quenching free radicals after irradiation. With respect to claims 138-140, the claims of Application ‘209 recite a radiation dose greater than 1 Mrad and a greater than 20 Mrad.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**Claims 124-127 and 135-140 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 124-129 of copending Application No. 10/696362.** Although the conflicting claims are not identical, they are not patentably distinct from each other because the same methods steps, i.e. heating above the melting temperature and irradiating the UHMWPE are set forth in the claims of '362 and in the instant claims. The step of heating above the melting temperature set forth in the claims of '362 is encompassed by the step of pre-annealing at a temperature less than the decomposition temperature of polyethylene set forth in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

*Conclusion*

**Any inquiry concerning this communication or earlier communications from the examiner should be directed to /SUSAN W. BERMAN/ whose telephone number is (571)272-1067. The examiner can normally be reached on M-F 9:30-6:00.**

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on 571 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SB  
2/22/2012

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